

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS**  
**(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## **Esmya 5 mg tablets**

The active ingredient and its concentration: **Ulipristal acetate 5 mg**

For a detailed list of inactive ingredients see section 6.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for girls and female adolescents under 18 years of age.

### **1. What is the medicine intended for?**

Esmya is a medicine intended for treatment of moderate to severe symptoms of uterine myomas in adult women (over 18 years old) of childbearing age, before surgery for removal of uterine myomas.

Uterine myomas are benign tumors of the uterine muscle tissue that might cause increased menstrual bleeding, pelvic pain (abdominal discomfort) and pressure on different organs.

Therapeutic class: A selective modulator of progesterone receptor.

### **2. Before using the medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to Ulipristal acetate (the active ingredient) or any of the additional components, which the medicine contains (see section 6).
- You are pregnant or breastfeeding.
- You suffer from a vaginal bleeding not due to uterine myomas.
- You suffer from uterine cancer, cervical, ovarian or breast cancer.

### **! Special warnings regarding the use of the medicine:**

- If you are using hormonal contraceptives (such as birth control pills) (see below "using other medicines with Esmya"), you should use another reliable physical contraceptive (such as condoms) during the treatment with Esmya.
- If you are suffering from a liver or kidney disease, you should consult a doctor before taking this medicine.
- If you are suffering from a severe asthma, you should consult a doctor before taking this medicine. It is possible that treatment with Esmya may not be appropriate for you.
- The medicine causes a significant reduction and even cessation of menstrual bleeding during the first 10 days of treatment. If you still suffer from increased menstrual bleeding, you should consult a doctor.

Menstruation usually returns within 4 weeks of discontinuing Esmya treatment. The uterine mucosa can become thicker or change as a result of taking Esmya. These changes will be gone after treatment has been discontinued and the menstruation has returned.

### **! Girls and female adolescents**

Esmya is not intended for girls and female adolescents under the age of 18.

**! If you are taking or have recently taken other medicines including non-prescription medicines, food supplements, vitamins and herbal supplements, tell the physician or the pharmacist.** Especially inform the doctor or pharmacist before starting treatment with Esmya if you are taking one of the following medicines:

These medicines may affect Esmya's action, or these medicines' action may be affected by Esmya.

- Certain medicines for treatment of heart conditions (such as Digoxin).
- Certain medicines for prevention of stroke and blood clots (such as Dabigatran).
- Certain anti-epileptic medicines (such as Phenytoin, Fosphenytoin, Carbamazepine, Phenobarbital, Oxcarbazepine, Primidone).
- Certain medicines for treatment of an HIV (Human Immunodeficiency Virus) infection (such as Ritonavir, Efavirenz, Nevirapine).

- Medicines for treatment of certain bacterial infections (such as Telithromycin, Clarithromycin, Rifampicin, Erythromycin, Rifabutin).
- Medicines for treatment of fungal infections (such as Ketoconazole (except for shampoo) and Itraconazole).
- Herbal medicines containing Hypericum (St. John's Wort) for treatment of depression and anxiety.
- Certain medicines for treatment of depression (such as Nefazodone).
- Certain medicines for treatment of hypertension (such as Verapamil).
- Esmya may reduce the efficacy of hormonal contraceptives (e.g. birth control pills). In addition, hormonal contraceptives and progestogens (such as Norethindrone or Levonorgestrel) may reduce the efficacy of Esmya. Therefore, hormonal contraceptives are not recommended and an alternative reliable physical contraceptive (such as condoms) should be used during treatment with Esmya.

### **! Use of the medicine and food**

You should avoid drinking grapefruit juice during treatment with Esmya.

### **! Pregnancy and breastfeeding**

Do not take Esmya during pregnancy. Treatment with Esmya may disrupt the pregnancy (it is unknown whether Esmya can harm your fetus or lead to an abortion). If you become pregnant during treatment, you should discontinue the medicine immediately and consult a doctor.

Esmya may reduce the efficacy of certain hormonal contraceptives (see "Using other medicines with Esmya").

Esmya is transferred through breast milk, so you should not breastfeed during treatment with Esmya.

### **! Driving and operating machinery**

Using this medicine may cause a slight dizziness (see section 4, side effects). If you feel this effect, do not drive a vehicle or operate dangerous machinery.

### **3. How should you use the medicine?**

Always use according to the doctor's instructions. Consult with the doctor or pharmacist if you are unsure.

The dosage and treatment regimen will be determined by your doctor only.

The usual dosage is: one tablet of Esmya 5 mg per day, for a treatment cycle up to 3 months.

The 3-months treatment may be repeated only once. If an additional 3-months treatment with Esmya has been recommended to you by the doctor, you should start taking it as early as possible during the second menstrual cycle after completion of the first cycle.

You should start treatment during the first week of the menstrual cycle.

The medicine should be taken with water. The medicine may be taken with or without food.

#### **Do not exceed the recommended dose.**

**If you accidentally take a higher dosage:** Data on Esmya's effect when several doses are taken at once are limited. There were no reports about severe side effects when taking several doses of Esmya at the same time. Nevertheless, you should consult a doctor if you have taken a dosage higher than recommended.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you.

**If you forgot to take the medicine,** and less than 12 hours have passed since the time when you were supposed to take the medicine, you should take the medicine as soon as you have remembered. If more than 12 hours have passed since the time when you were supposed to take the medicine, you should skip the forgotten dose and take the next dose at the usual time. Do not take a double dose in order to compensate for a forgotten dose.

**If you discontinue the treatment:** Follow the treatment as recommended by the doctor. You should take the medicine every day for three months continuously. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor, because the symptoms may occur again.

Do not take medicines in the dark!

Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

#### **4. Side effects**

As with any medicine, use of Esmya may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

**Side effects occurring very frequently (may occur in more than one patient out of 10 patients):**

- Reduction or lack of menstrual bleeding.
- Thickening of the uterine mucosa.

**Side effects occurring frequently (may occur in up to one patient out of 10 patients):**

- Headache.
- Sensation of giddiness (vertigo).
- Abdominal pain, Nausea.
- Acne.
- Muscle and bone pain.
- A fluid sack in the ovaries (ovarian cyst), increased sensitivity or pain in breasts, lower abdominal (pelvic) pain.
- Hot flashes.
- Tiredness.
- Weight gain.

**Side effects occurring infrequently (may occur in up to one patient out of 100 patients):**

- Anxiety.
- Mood swings.
- Dizziness.

- Dry mouth, constipation.
- Loss of hair, dry skin, increased sweating.
- Back pain.
- Urinary leaks.
- Vaginal discharge, abnormal vaginal bleeding, uterine bleeding.
- Feeling of discomfort in breasts.
- Swelling due to accumulation of fluids (edema).
- Extreme fatigue.
- Rise in blood cholesterol level, rise in blood lipids (triglycerides) level (according to blood tests).

**Side effects occurring rarely (may occur in up to one patient out of 1000 patients):**

- Nose bleeding.
- Indigestion, swelling in the digestive system.
- Rupture of fluid sack in the ovary (a rupture of an existing ovarian cyst).
- Breasts swelling.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

You can also report side effects to CTS Ltd. With this report, you are helping to gather information about the medicine's safety.

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton and the blister package. The expiry date refers to the last day of that month.
- Store below 25°C, in the original package to protect from light.

## **6. Additional information**

- In addition to the active ingredient the medicine also contains:  
Microcrystalline cellulose, Mannitol, Talc, Croscarmellose Sodium, Magnesium Stearate
- What does the medicine look like and what is the content of the package: a round, biconvex, white to off-white tablet, with 7 mm diameter and "ES5" engraved on one side. The tablets are packed in blisters. Each blister contains 14 tablets. The blisters are packed in a carton pack. Each carton pack contains a total of 28 or 84 tablets.
- License holder and importer: CTS Ltd., 4 Haharash St., Hod Hasharon.
- Manufacturer: HRA Pharma labs, Paris, France.
- This leaflet was checked and approved by the Ministry of Health in: 01/2016
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-35-34283